IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

JOHNSON & JOHNSON'S AND ETHICON'S MEMORANDUM IN SUPPORT OF MOTION TO REVISE CASE MANAGEMENT PROCEDURES RELATED TO STATUTE OF LIMITATION AND ESTOPPEL DEFENSES

Johnson & Johnson and Ethicon noted in the Memorandum in Support of Motion to Revise Case Management Procedures and for Discovery Related to Plaintiff Solicitation [Doc. 1419, filed January 15, 2015] the need to implement mechanisms to expeditiously identify and dispose of legally impermissible claims. To that end, Johnson & Johnson and Ethicon request entry of a Case Management Order that requires each Plaintiff to submit specific information and documentation so that Defendants can confirm use of an Ethicon product and documented complaints to a physician of a potentially compensable injury. Further, medical records and other information can assist in identifying claims that are barred by the applicable limitations period, that belong to bankruptcy trustee rather than the plaintiffs, and that might be precluded by judicial estoppel.

1. More than two years ago, the parties negotiated and the Court entered PTO #17, requiring each plaintiff to submit a Plaintiff Profile Form and with the PPF "hard copies or electronic files of all medical records in their possession or control, including, in particular, records that support product identification." Defendants contemplated this requirement would yield substantial

medical records that demonstrated each plaintiff's condition immediately prior to implant of a pelvic mesh device, provided specific product identification, and documented complaints to a physician of a potentially compensable injury. In practice, Defendants have routinely received with PPFs only a single page of medical records containing a product identification sticker or a single page operative report.

2. The most basic piece of evidence that every plaintiff ought to have prior to filing suit (except in an exceptional case) is proof that she has been implanted with an Ethicon pelvic mesh device. To that end, we ask the Court to implement new case management procedures to require each plaintiff to provide the complete surgical operative report for the implantation of the Ethicon device. In addition, if the operative report does not include the product identifier code showing the particular Ethicon device implanted, the plaintiff must also provide the specific medical record or hospital invoice that does contain the product code. Any plaintiff whose case has been pending in the MDL more than 60 days (and thus should already have submitted a Plaintiff Profile Form) should submit this information – if not included with the PPF – within 30 days of the date of the order. Any plaintiff presently in this MDL but whose PPF is not yet due mush include these records with her PPF. Any plaintiff who joins this MDL after the date of the Order should provide these records within 20 days of being assigned a case number in the MDL. The Court should dismiss with prejudice every plaintiff who fails to timely comply.

3. Information provided by Plaintiffs to date shows that at least 10,000 plaintiffs have had no surgical revision. A substantial number of MDL participants may have no documented complaint of injury before a decision to file suit. Defendants ask the Court to require every plaintiff to provide all physician office notes addressing the indications for the implant, going back at least 1 year prior to the surgery, and physician notes for one year

following the implant, as well as all medical records reflecting any complaint to a physician of the injuries allegedly caused by the device, including but not limited to records evidencing excision, revision or explant of the mesh product (either in a physician's office or under regional or general anesthesia). Any plaintiff whose case has been pending in the MDL more than 60 days (and thus should already have submitted a Plaintiff Profile Form) should submit this information – if not included with the PPF – within 30 days of the date of the order. Any plaintiff presently in this MDL but whose PPF is not yet due, and any plaintiff who joins this MDL after the date of the Order, must include these specific records with her PPF. Court should dismiss with prejudice every plaintiff who fails to timely comply.

4. Forty-seven states and the District of Columbia have statutes of limitation of 4 years or less. Almost three quarters of Plaintiffs in this MDL (17,000) filed suit more than four years after the date of their implant. Further, out of the 8,900 Plaintiffs who provided information about an alleged mesh-related revision procedure, close to 4,000 filed suit more than 4 years after that procedure. Relying almost exclusively upon information in the PPFs, Johnson & Johnson and Ethicon believe as many as half the pending claims may be time-barred. Complete medical records for each Plaintiff should allow Johnson & Johnson and Ethicon to determine the limitation period applicable to each Plaintiff, to identify any Plaintiff that has not complied with her state's limitation period and to then advise the Court of untimely claims. In the event that any Plaintiff underwent a revision surgery beyond the period of limitation applicable to her claim, the Court should require Plaintiff to show cause why her claim should not be dismissed with prejudice as untimely.

5. More than 6,000 Plaintiffs indicated on their PPFs that they have filed for bankruptcy protection, yet most provided little or no information beyond that affirmative

response. Johnson & Johnson and Ethicon must be permitted to obtain some basic information concerning any Plaintiff who has filed bankruptcy in order to evaluate whether she can pursue a claim in this MDL. In order to identify any Plaintiff who lacks standing to pursue her claims or who is judicially estopped from doing so, every Plaintiff should provide evidence that her suit is not barred by judicial estoppel or controlled by a bankruptcy court. Each Plaintiff should be required to provide an affidavit addressing whether she filed for bankruptcy protection after the date of her implant surgery. Every Plaintiff who filed for bankruptcy protection after the date of her implant surgery should also attach with the affidavit a copy of the bankruptcy petition, schedules and statement of financial affairs, along with all amendments thereto, and provide evidence that the Plaintiff has standing to pursue the claim in this MDL in light of the bankruptcy filing. Any plaintiff whose case has been pending in the MDL more than 60 days (and thus should already have submitted a Plaintiff Profile Form) should submit this information within 30 days of the date of the order. Any plaintiff presently in this MDL but whose PPF is not yet due, and any plaintiff who joins this MDL after the date of the Order, must include this information with her PPF. The Court should dismiss with prejudice every plaintiff who fails to timely comply.

6. Johnson & Johnson and Ethicon earlier expressed their interest in moving this litigation forward, and are prepared to do so. Nearly half of the cases pending in MDL 2327 involve only the TVT or TVT-O devices. Johnson & Johnson and Ethicon propose the Court randomly select 200 TVT and/or TVT-O cases where the plaintiff had timely submitted by January 15, 2015, a substantially complete Plaintiff Profile Form (PPF) with medical records and authorizations, and allow case-specific discovery of those claims. Defendants suggest the following preliminary schedule:

1. **February 6, 2015.** Defendants submit to the Court a list of all plaintiffs who qualify for this discovery pool (allege injury from a single product, either a TVT or TVT-O device; timely submitted a substantially complete PPF by January 15, 2015);
2. **February 13, 2015**. The Court will select 200 cases from that list for discovery.
3. **March 13, 2015.** Plaintiffs selected as part of the discovery pool shall provide a the medical and other records identified in Paragraphs 2,3, and 5 above (if not already provided) and respond to the Requests for Product of Documents that are part of the Plaintiff Fact Sheet. If a plaintiff fails to provide these documents by this deadline, Ethicon has the option to file a Request for a Show Cause Order why the case should not be dismissed with prejudice.
4. **April 13, 2015.** Defendants and Plaintiffs' Liaison Counsel must submit a proposed agreed docket control order governing timing and scope of deposition discovery of the 200 cases selected by the Court and/or submit to the Court unresolved issues related to the conduct and timing of such discovery. The docket control order should contemplate trial(s) in early **November 2015**.
5. **May 13, 2015** Ethicon shall provide the information requested in Sections I - III of the Defendant Fact Sheet ("DFS") approved in PTO #41 and respond to Document Requests A, B, D, and E for every Plaintiff then in the discovery pool and not subject of a pending Request for a Show Cause Order or a Show Cause Order.

Respectfully submitted,

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

Counsel for Ethicon, Inc. and Johnson & Johnson

CERTIFICATE OF SERVICE

I certify that on February 2, 2015, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones

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